

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the following comments. Claims 50-115 were pending. Claims 50-70, 77-105, and 108-115 have been withdrawn. Claim 71 has been amended. It is believed that no new matter has been added. Accordingly, claims 71-76 and 106-107 are pending.

Statement regarding Information Disclosure Statement

It is unclear what the Examiner is stating in regards to an information disclosure statement since it appears that an IDS has not been filed.

Rejection of claims 71-76, 106 and 107 under enablement

In order to support the enablement rejection, the Examiner stated that Figures 17 and 18 fail to show any statistical differences in the blood coagulation time. Specifically, the Examiner stated that Figure 17 shows that the error bars of control group 1 (without plasmid) extensively overlap the values attached for all of the test groups. However, it appears that between Groups I and 5 (with plasmid) show a statistical difference because the two groups do not overlap extensively. Furthermore, it appears in regards to Figure 18, overall, Group 5 seems to show a longer coagulation time than Group 1.

In regards to the Examiner stating that articles show that gene therapy is

unpredictable, the articles cited by the Examiner are outdated (from 1997 and older) and do not represent the advances that have been made at the time of the filing date of the claimed invention (January 16, 2003). It is, therefore, respectfully requested that the Examiner reconsider and withdraw this rejection.

Rejection of claims 71-76, 106 and 107 under indefiniteness

Claim 71 has been amended to read in part, "wherein one of said at least one HRE's does not regulate the transgene," rather than saying, "functionally linked." It is assumed that "not functionally linked" means that the response element does not regulate transcription of the transgene.

In regards to the Examiner stating that claims 75 and 76 are indefinite, it is believed that the phrase "composition of matter" is commonly used and accepted in patent claims.

It is, therefore, respectfully requested that the Examiner reconsider and withdraw this rejection.

Rejection of claims 71 and 73-76 as being anticipated by Schwartz et al. (U.S. Patent No. 5,298,422).

In order to show anticipation, the reference must teach or suggest every element of the claimed invention. Figure 3 of Schwartz et al. does not seem to even contain a hormone response element. Even if it did, it is unclear from Figure 3 that at least one

hormone response element does not regulate the transgene as in our claimed invention. In fact, in Figure 8 of Schwartz et al., it appears to describes the response hormone element (Vitamin D) regulating the transgene, which is different from our claimed invention.

Rejection of claims 71-76, 106 and 107 as being anticipated by Schwartz et al., U.S. Patent No. 5,756,264).

It does not appear that Figure 11 (which the examiner refers to) of Schwartz et al., describes at least one hormone response element which does not regulate a transgene as to our claimed invention. Thus, the reference seems to fail to teach or suggest every element of the claimed invention.

It is, therefore, respectfully requested that the Examiner reconsider and withdraw these anticipation rejections.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the above requires an extension of time, Applicant respectfully requests that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS MC LAUGHLIN & MARCUS, P.A.

By _____


Paul Lim
Reg. No. 55,383
875 Third Avenue
18th Floor
New York, New York 10022
Tel 212-808-0700